

## **REMARKS**

### **Currently Pending Claims**

Claims 47-50 and 52-69 are pending in the application.

### **Amendments to the Claims**

Claim 47 is amended to recite a pure botanical triterpene. Support for the amendment to recite a triterpene isolated from plants may be found in the application as filed at page 2, ¶ [0004] and exemplified at page 11, ¶ [0049]. Claim 47 is also amended to require docosahexaenoic acid in an amount of less than 0.1%. Support for this amendment may be found for example at page 3, ¶[0010]. Claim 48 is amended to comprise no docosahexaenoic acid. Support for this amendment may be found for example at page 1, ¶[0003]; p. 6, ¶[0025]; p. 7, ¶[0028]; and p. 13, ¶[0056]. Claims 65 and 66 are accordingly, similarly amended to incorporate the same limitations as newly amended claim 47. Claims 65 has been amended to recite a liquid, paste, tablet or capsule further comprising less than 0.01% docosahexaenoic acid. Claim 66 has been amended to recite a method for making a formulation further comprising less than 0.01% docosahexaenoic acid. Support for these claims may be found at page 13, ¶[0056].

Claim 51 is cancelled.

Claim 53 and 66-67 are withdrawn.

Claims 68 and 69 are new.

### **Claim objections**

Claim 65 has been amended to correct the typographic error.

### **Rejection under 35 U.S.C. 112, Written Description**

The examiner has rejected claims 47-52 and 57-65 for lack of written description under 35 U.S.C. 112, first paragraph. Specifically, the examiner has indicated that the terms “triterpene or an ester thereof ... may not suffice to meet the written description requirement”.

Claim 47 is amended to recite a botanical triterpene. Support for a triterpene isolated from plants may be found in the application as filed at page 2, ¶[0004] and exemplified at page 11, ¶

[0049]. The applicant respectfully asserts that those skilled in the art would have a clear understanding of what botanical or plant-origin triterpenes are, particularly as they do not have the structure of the squalene triterpene (2,6,10,15,19,23-hexamethyl-2,6,10,14,18,22-tetracosahexaene) found in shark liver oil.

The examiner has also stated that the specification does not provide a reasonably representative disclosure of useful triterpene or esters thereof generally a potentially huge genus inclusive of many different compounds having widely divergent structures and functions (the Office Action at page 5).

The applicant respectfully disagrees. The botanical triterpenes of amended claim 47 are, the applicant believes, adequately disclosed in the application as filed which describes the naturally occurring triterpenes of the invention as being isolated from a variety of plants including marigold, bean caper flowering plants (Zygophyllaceae), saffron thistle (Carthamus lanatus), evening primrose, and rose (Pursh comminus) (see page 2, ¶[0004]), as well as the Example describing extraction of triterpenes from marigolds (see the Example at page 11, ¶[0049]). Applicant requests this rejection be withdrawn.

#### **Rejection under 35 U.S.C. 112, Indefiniteness**

The examiner has rejected claims 47 and 49-65 as being indefinite under 35 U.S.C. 112, second paragraph. Specifically, the examiner takes issue with the use of the word “substantially” in pending claims 47 and 65 and the word “pure” in pending claim 51.

The applicant has amended claim 47 to remove the word “substantially”. Although the applicant contends that the meaning of “substantially no docosahexaenoic acid” was clear according to the application as filed, meaning less than about 0.1% docosahexaenoic acid (see the application at page 3, ¶ [00109]), the applicant has duly amended claim 47 to recite “less than about 0.1% docosahexaenoic acid” and claim 48 to recite “no docosahexaenoic acid”.

The applicant has cancelled claim 51 as being redundant over newly amended claim 47 which recites “no docosahexaenoic acid”, thus removing the cause of the examiner’s rejection of the claim reciting the word “pure”.

However, it would be understood by those skilled in the art that a synthetic eicosapentaenoic acid or a synthetic ester of eicosapentaenoic acid, or a combination thereof,

could be formed as having no docosahexaenoic acid. The application states “if naturally occurring, the eicosapentaenoic acid may be ultra pure, that is, it is substantially free of any impurities. Such impurities may include docosahexaenoic acid.” See application as filed at page 1, ¶ [0003]. The applicant has also indicated how to extract eicosapentaenoic acid from fish oil to be extracted either substantially free of docosahexaenoic acid or with no docosahexaenoic acid (see the application at page 11, ¶ [0049]). Thus, those skilled in the art may obtain a pure eicosapentaenoic acid extract if required. Applicant requests this rejection be withdrawn.

### **Rejection under 35 U.S.C. 102, Anticipation**

The examiner has rejected claims 47-52, 54-63 and 65 for under 35 U.S.C. 102(b) as being anticipated by Horrobin et al., specifically stating that “The reference anticipates the instant claims insofar as it discloses compositions for the skin comprising eicosapentaenoic acid; a triterpene primrose oil”.

The applicant respectfully disagrees that the reference anticipates the instant claims. The reference makes no mention of docosahexaenoic acid, let alone extracting eicosapentaenoic acid substantially free of docosahexaenoic acid or with no docosahexaenoic acid. By contrast, the instant application states: “It is considered that in some circumstances docosahexaenoic acid can inhibit some of the benefits of eicosapentaenoic acid or an ester thereof. Known compositions or formulations containing eicosapentaenoic acid, such as fish oils, also contain docosahexaenoic acid. In order to obtain eicosapentaenoic acid which is free or substantially free of docosahexaenoic acid from fish oil, the eicosapentaenoic acid must be extracted from the fish oil.” (see the application as filed at page 3, ¶ [0010]). Thus, in the instant invention, extraction of eicosapentaenoic acid from fish oil is carried out in order to obtain it free of docosahexaenoic acid (see the instant application at page 11, ¶ [0049]: “A method of extracting eicosapentaenoic acid from fish oil is described in *Enzyme Microb Technol.* 2000 Apr 1; 26(7) : 516-529. By using this method eicosapentaenoic acid is extracted substantially free of docosahexaenoic acid or with no docosahexaenoic acid”).

Therefore, it cannot be concluded that the compounds of Horrobin et al. are free of, or contain less than 0.1% of, docosahexaenoic acid, as disclosed in the instant formulation of amended claims 47 and 48.

Thus, amended claims 47 and 48 cannot be said to be anticipated by Horrobin et al. Dependent claims 49-64 depend either directly or indirectly from newly amended claim 47, claims 49-52 and 54-63 are not anticipated by Horrobin et al. Newly amended claim 65 is not anticipated by Horrobin for the reasons stated above for amended claim 47. For the reasons discussed above for newly amended claim 48, new claims 68 and 69 would not be anticipated by Horrobin et al.

The examiner also has rejected claims 47-52 and 57-65 under 35 U.S.C. 102(b) as being anticipated by Bettel et al.

The applicant respectfully disagrees. Bettel et al. disclose compositions comprising shark liver oil. Shark liver oil contains squalene which is not a botanical triterpene, and moreover, contains the long-chain n-3 polyunsaturated fatty acid DHA (docosahexaenoic acid) which can only be present in amounts less than about 0.1% in amended claim 47, and which is excluded by claim 48, and in fact disclosed as being specifically excluded in the application as filed, as discussed above (see page 11 at lines ¶ [0049]).

Newly amended claim 47 recites a formulation restricted to less than 0.01% docosahexaenoic acid. Since Bettel specifically discloses the incorporation of docosahexaenoic acid (see Bettel at paragraph [0063]) and is completely silent about any suggestion of removing docosahexaenoic acid from eicosapentaenoic acid, it cannot be said that Bettel even suggests a possible formulation in which docosahexaenoic acid limited to the amount of less than 0.1%, recited in newly amended claim 47. Therefore, the applicant contends that Bettel et al. does not anticipate newly amended claim 47.

Therefore, newly amended claim 47 cannot be said to be anticipated by Bettel et al. Dependent claims 49-64 depend either directly or indirectly from newly amended claim 47 and therefore, claims 49-52 and 57-64 cannot be said to be anticipated by Bettel et al. Newly amended claim 65 has been amended to incorporate the limitations of newly amended claim 47, and therefore cannot be said to be anticipated by Bettel et al.

Therefore, the applicant respectfully asserts that the claims are patentable over Horrobin et al., and over Bettel et al. The applicant respectfully requests that the examiner reconsider the pending claims in the light of the argument set forth above.

The applicant believes the claims are currently allowable and requests reconsideration of the claims. The examiner is also invited to call the undersigned attorney if it is believed that such a communication will move the case forward.

In view of the foregoing, applicant submits that the instant claims are in condition for allowance. Early and favorable action is earnestly solicited. The fee for a two (2) month extension of time is submitted herewith. In the event there are any fees due and owing in connection with this matter, please charge same to our Deposit Account No. 11-0223.

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Respectfully submitted,

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